From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY CHAS. HUDE A/S Sagstyr 33, H.C. Andersens Boulevard ZHECK WRITTEN OPINION 1780 Copenhagen V DANEMARK (PCT Rule 66) 1 3 APR. 2004 AS 400 TII F Date of maille 08.04.2004 (dayanontnayear) Applicant's or agent's file reference REPLY DUE within 3 month(s) from the above date of mailing Priority date (day/month/year) International filing date (day/month/year) International application No. 02.07.2002 02.07.2003 PCT/DK 03/00462 International Patent Classification (IPC) or both national classification and IPC A23K1/16, A23K1/16 Applicant HANSEN, John Erik This written opinion is the first drawn up by this International Preliminary Examining Authority. This opinion contains indications relating to the following items: 2  $\boxtimes$ Basis of the opinion 11  $\Box$ Priority Non-establishment of opinion with regard to novelty, inventive step and industrial applicability 111 Lack of unity of invention IV Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability;  $\boxtimes$ citations and explanations supporting such statement Certain documents cited Certain defects in the international application VII VIII 🗆 Certain observations on the international application The applicant is hereby invited to reply to this opinion See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d). When? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66 3 How? For the form and the language of the amendments, see Rules 66 8 and 66 9. For an additional opportunity to submit amendments, see Rule 66.4. Also: For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66 6. If no reply is filed, the international preliminary examination report will be established on the basis of this opinion. The final date by which the international preliminary examination report must be established according to Rule 69.2 is:

Name and mailing address of the international preliminary examining authority:



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Formalities officer (Incl. extension of time limits) Rossi, C Tetephone No. +31 70 340-3322



# WRITTEN OPINION

		the		

1.	With regard to the elements of the international application (Replacement sheets which have been furnished	ed to
	the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally	
	filed"):	

	Des	cription, Pages							
	1-9		as originally filed						
	1-5		ao ong many mod						
	Cla	ims, Numbers							
	1-5	·	as originally filed						
2.	Witl lạng	With regard to the language, all the elements marked above were available or furnished to this Authority in the anguage in which the international application was filed, unless otherwise indicated under this item.							
	The	These elements were available or furnished to this Authority in the following language: , which is:							
			anslation furnished for the purposes of the international search (under Rule 23.1(b)).						
			anslation furnished for the purposes of international preliminary examination (under						
3.	With inte	n regard to any <b>nucl</b> e rnational preliminary	otide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:						
		contained in the inte	rnational application in written form.						
		filed together with th	e international application in computer readable form.	•					
		furnished subsequently to this Authority in written form.							
		furnished subsequently to this Authority in computer readable form.							
	□	The statement that the international a	he subsequently furnished written sequence listing does not go beyond the disclosupplication as filed has been furnished.	re					
		The statement that the listing has been furn	he information recorded in computer readable form is identical to the written sequer ished.	ce					
4.	The	he amendments have resulted in the cancellation of:							
		the description,	pages:						
		the claims,	Nos.:						
		the drawings,	sheets:						
5.		This opinion has be been considered to	en established as if (some of) the amendments had not been made, since they have go beyond the disclosure as filed (Rule 70.2(c)).						
6.	Add	dditional observations, if necessary:							
٧.	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement								
1.	Stat	ement							

# WRITTEN OPINION

International application No.

PCT/DK 03/00462

Novelty (N)

Claims

Inventive step (IS)

Claims

Industrial applicability (IA)

Claims

1-5

2. Citations and explanations

see separate sheet

## Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-6 156 333 (LANGREHR JANA S) 5 December 2000 (2000-12-05)

D2: US-A-5 976 568 (RILEY PATRICIA A) 2 November 1999 (1999-11-02)

2. The present application does not meet the requirements of Article 33 (3) PCT because the subject-matter of independent claim 1 does not involve an inventive step.

The document D1 describes feed compositions for improving the immune status of animals which may contain biotin (2.5-10%), allicin (<2%) and vitamin E, vitamin C and selenium (see D1; column 3, line 7-67, column 11, paragraph 3).

The document D2 discloses a system containing biotin, garlic, vitamin C, vitamin E, and selenium (see D2; claim 3).

The subject-matter of independent claim 1 consists in the specification of a kit containing a selection of a composition from the range of values described in the documents D1-D2. Such a selection can only be regarded as inventive, if the chosen composition presents unexpected effects or properties in relation to the rest of the range. However, no such effects or properties are indicated in the application. Hence no inventive step is present in the subject-matter of claim 1.

3. Dependent claims 2-5 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, as the features of these dependent claims have already been employed for the same purpose in similar compositions and processes (see whole document D1; D2).



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7 July 2004

Dear Sirs

International patent application No PCT/DK2003/00462

Applicant: John Erik Hansen

International classification: IPC A23K1/16

My ref: 77874 BC/ge

In reply to the first Written Opinion dated 8 April 2004 I shall hereby on behalf of the Applicant make the following remarks.

The Examiner has cited two publications, ie. D1: US-A-6,156,133 (Langrehr) and D2: US-A-5,976,568 (Riley), and states that the present application does not meet the requirements of Article 33(3) PCT because the subject-matter of claim 1 does not involve an inventive step. D1 discloses feed compositions for improving the immune status of animals, said compositions containing biotin (2.5-10 %), allicin (<2 %) and vitamin E, vitamin C and selenium. D2 discloses a system containing biotin, garlic, vitamin C, vitamin E and selenium.

The Examiner correctly states that the subject-matter of claim 1 of the present application relates to a kit containing a selection of a composition from the range of values described in Dl and D2 However, The Examiner does not mention that the product according to D1 is a specific feed fortifier and enhancer for preruminant, bovine calves comprising animal plasma as well as other ingredients, including biotin, allicin, vitamins and selenium. The product accord-



ing to D2 is a modular system of dietary supplement compositions for use on human beings.

Thus, it can be ascertained that neither D1 nor D2 are aimed at the conditions and the target group of animals at which the present application is aimed.

It can also be ascertained that the vitamin-containing system of the present application demonstrates significant advantages when administered to certain groups of animals in accordance with an administration plan set out in the application.

These advantages can be illustrated by means of the following examples:

## 1. Mink

A public inquiry among mink farmers in Denmark indicates that 40 % of the respondents find the condition of the animals unchanged, whereas 60 % record an improvement in the condition of the animals, particularly in relation to the so-called Greasy Kits Syndrome. This condition causes unthriftiness, reduced weight gain and a mortality rate of up to 50 %. The cause of the syndrome is not yet known, but it is supposed to be affected by the development of the digestive tract.

The general mortality among minks (both adult animals and young ones) is indicated as being declining when kit 2 is used in combination with a feed additive in the form of natural antioxidants (blueberries, allicin and roots).

#### Milch cows

40-50 % of milch cows worldwide become infected with the disease digital dermatitis (corresponding to about 180 million animals) causing a decline in the milk production of up to 40 %. In a Danish herd of more than 4,000 cows, the situation has stabilized, ie. no new incidents are found, and more than half the herd has been cured after treatment with kit 1 followed by treatment with kit 2.

## Broilers

3

Chas.Hude

On the biggest chicken farm in Denmark having an annual production of approx. 12 million

chickens, a considerable improvement of the immune response of the animals within this animal

group has been recorded after treatment with kit 2 according to the invention. An effect was re-

corded within 12 days in the form of a considerable weight gain of 20 g per chicken. The

weight gain was approx. 100 g per chicken on the time of slaughtering (after 43 days), thus

yielding increased profit of approx. 10 % for the farmer as well as improved quality of life for

the animals.

Another aspect is that the useful parts of the vitamin-containing system according to the inven-

tion are accumulated in the liver of the chicken, from where they can be extracted and used

again.

Pigs

Several positive responses have been received from large-scale pig breeders reporting that

treatment with kit 2 and a natural feed additive is effective against diarrhoea and a too high in-

tensity of infection. In this way, it becomes possible to reduce the use of medicine considerably

and increase the quality of life for the animals – and thus ensure the ultimate product quality.

On the basis of the above, it is the opinion of the Applicant that it has been substantiated that

the vitamin-containing system according to the invention leads to unexpected positive effects

which could not have been anticipated on the basis of the prior art, including the cited docu-

ments D1 and D2.

I hope that the Examiner agrees with this view and look forward to receiving a positive Prelimi-

nary Examination Report.

Yours faithfully

Bent Christensen

Representative of the applicant

Enc: Form 1038